UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT		ATTORNEY DOCKET NO.
07/313,911	02/23/89	SHEPHERD	A	UTSK097BAH

ARNOLD, WHITE & DURKEE
P.O. BOX 4433
HOUSTON, TX 77210

EXAMINER	
ROSENBERGER, R	
ART UNIT	PAPER NUMBER
2505	20

DATE MAILED: 04/06/92

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents.

The reply brief filed 27 January 1992 has been entered and considered but no further response by the Examiner is deemed necessary. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

R. A. Rosenberger

RICHARD A. ROSENBERGER
EXAMINER
ART UNIT 255

MAILED

Art Unit 2505

JUL 30 1992

Paper No. 21

Appeal No. 92-0991

dem

PAT & TM OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

ON BRIEF

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte A. P. Shepherd
and
John M. Steinke

Application for Patent filed February 23, 1989, Serial No. 313,911. Method And Apparatus For Direct Measurement Of Hemoglobin Species In Whole Blood.

Kevin L. Daffer et al. for Appellants.

Primary Examiner - Richard A. Rosenberger

Before Thomas, Hairston and Cardillo, Examiners-in-Chief.

Cardillo, Examiner-in-Chief.

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 to 12, all of the claims remaining in this application. The amendment after final rejection (Paper No. 10, filed January 29, 1991) has been entered.

The claimed invention relates to a method of determining concentrations of constituent components of whole undiluted blood. Representative claim 1, the sole independent claim before us, is reproduced as follows:

1. A method of determining concentrations of constituent components of whole undiluted blood, including:

generating a plurality of radiation frequencies each determined to distinguish one said constituent component from another said constituent component, and to minimize the effect of radiation scattering and to maximize radiation absorbance by whole, undiluted blood;

irradiating a sample of whole, undiluted blood with at least three of said radiation frequencies, through a depth of said sample chosen to minimize radiation scattering by whole, undiluted blood;

detecting intensities of said radiation frequencies, after passing through said depth of said sample, at a distance from said sample, and over a detecting area, both chosen to minimize the effect of radiation scattering by whole, undiluted blood; and

calculating concentrations of each of at least three said constituent components of said sample of whole, undiluted blood, based upon detected intensities of said radiation frequencies, and upon predetermined molar extinction coefficients for each of said constituent components at each of said radiation frequencies.

The references of record relied on are:

Shibata et al. (Shibata)	3,516,746	Jun. 23, 1970
Brown et al. (Brown)	4,134,678	Jan. 16, 1979

Anderson et al. (Anderson), "Light-absorbing and Scattering Properties of Non-haemolysed Blood," Phys. Med. Biol., Vol. 12, No. 2, 1967, pp 173-184.

Claims 1 to 12 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner offers Anderson considered with Brown and further adds Shibata as to claims 3 to 5.

Rather than repeating the arguments of the appellants or the examiner, we make reference to the briefs and the answer for the details thereof.

OPINION

At the outset we note that appellants have presented one group of dependent claims (2 to 7) which are indicated to stand or fall with claim 1 (main brief, page 3) while claims 1 and 8 to 12 are indicated to be separately argued. Accordingly, each of the dependent claims 2 to 7 are treated as standing or falling with independent claim 1, while claims 1 and 8 to 12 are treated in terms of the specific arguments offered, infra.

We have carefully reviewed the record in this appeal and, as a result thereof, we find that the evidence relating to § 103 obviousness provided by the examiner is sufficient to support the rejection. Accordingly, we will sustain it for the reasons set forth below.

Appellants' major criticism of the examiner's position is that it does not take into account that "radiation frequencies are chosen not only to minimize deleterious scattering effects, but also to distinguish each constituent species from one another (claim 1)" (note, e.g., the bottom of page 4 of the main brief). This criticism is, however, flawed because it relies upon two underlying misconceptions which become clear when appellants' arguments are scrutinized in light of the disclosure.

The first of these underlying inconsistencies relates to the assertion of page 4 of the main brief that "[i]n this way, when the operator chooses a specific radiation frequency, he or she knows that the resultant optical density reading is directed to a particular constituent component or species." Thus, the implication is that each frequency is selected for directly reading a particular component or species of whole undiluted blood. Note also the similar statement of page 13 of the main brief "that the specific frequencies are chosen to measure corresponding specific constituent components" as well as the indication of page 5 of this brief that "certain frequencies produce better results when targeted [apparently one-to-one] to a certain constituent component." This apparent one-to-one rationale is also emphasized in terms of the reading of each frequency to alone determine its indications as to only one of the whole undiluted blood species on page 15 of the brief relative to the operator who is allowed "to discriminate measurements obtained from one component from those measurements of another component" (lines 6 and 7).

However, the disclosure is to the contrary because it sets forth no such one-to-one relationship as to only one frequency individually being used to read one component or species of whole undiluted blood. Instead, it is clear that simultaneous equations must be solved by controlling and

calculating unit 13 so that concentrations of the desired constituent components can be found (note the specification at page 8, line 28 to page 9, line 17 as to operation of unit 13).

Furthermore, appellant's specification does not itself set forth the programming of unit 13 to solve such multiple simultaneous equations, much less the equations themselves. Instead, it incorporates by reference (specification, page 6, lines 11-14) the disclosure of Brown as to such equations and appropriate solutions.

The specification does contain broad indications that the frequencies to be used, vis-à-vis gathering data to solve the Brown equations, should be selected to "maximize the measurement accuracy in distinguishing one hemoglobin species from another, and to minimize the sensitivity of the molar extinction coefficients of the individual hemoglobin species under consideration due to small changes in radiation wavelength" (specification, page 4, lines 18-23; also note page 6, lines 23-28) in addition to reducing scattering. However, absolutely no details or guidance as to achieving these desired results has been presented. Accordingly, the specification itself appears to presume and implicitly admit that the artisan is well aware of these goals and how to achieve them and that setting forth such details is therefore unnecessary. See In re Fox, 471 F.2d 1405, 176 USPQ 340 (CCPA 1973).

Besides the fact that appellants' specification presumes the artisan's repertoire includes sufficient tools (in terms of standard knowledge and ordinary skill to use it) to enable the selection of frequencies to be used with the equations of Brown to solve for corresponding blood components, we find only examples of some, apparently suitable, frequencies merely stated "to produce good measurement accuracy" (specification, page 7, lines 1-2) or to "have proven successful" (specification, page 7, lines 4-7) without any basis as to what constitutes "good measurement accuracy" or what the "proven successful" criteria limits are. Manifestly, the specification does not set forth the required degree of accuracy, or any other measure of success, in terms of the amount radiation absorption must exceed radiation scattering (decree of linearity), much less the specific maximization of measurement accuracy in distinguishing one species from another compared to other frequencies in the spectrum of possible choices. Further lacking is the degree that the sensitivity of the molar extinction coefficient has been minimized as to small variations in radiation wavelength much less what a very large molar extinction coefficient might be _vis-à-vis_ a merely large, medium or small one.

This brings us to the second underlying misconception noted above. In this respect, it is clear that appellants' arguments imply a criticality as to these broadly and vaguely

disclosed desired results that the specification merely sets forth in terms of examples merely implied to somehow satisfy such criteria. Indeed, nothing in the specification even establishes just how much greater absorbance must be than scattering such that, along with the other unknown criteria, particular groups of frequencies can be said "to produce good measurement accuracy" or to "have proven successful," as noted above.

In any event, it is clear that claim 1 merely recites that the radiation frequencies have been "determined to distinguish one said constituent component from another" and, thus, lacks any recital of optimizing this determination in the context of the above noted specification criteria, critical or otherwise. These specification desired results cannot be read into the broad pending claim language which is before us, as appellants appear to presume it can. See In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969).

Turning our attention to appellants' specific arguments (main brief, pages 9-22), we first note that we can find nothing in the noted Deere[1] analysis that sanctions determining the scope and content of the prior art in terms of only the express statements of each reference considered alone, as pages 10-12 of the main brief attempt to do it. The accepted approach,

[1]Graham v. Deere, 383 U.S. 1, 148 USPQ 459 (1966), incorrectly noted on page 10 of the main brief as 140 USPQ 459 (1966).

sanctioned by the courts, is that the teachings of all the references relied upon to support the rejection must be considered together as to what they would have reasonably suggested (both expressly and by implication) to the worker of ordinary or reasonable skill in the art (see, e.g. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981)). This is the manner in which we view the scope and content of the prior art.

However, before preceding in this manner, one last point as to Anderson requires clarification. In this regard, we find ample evidence that Anderson teaches the artisan the Figures 2, 5 and 6 showings as to 5050 Å (505 nm), 5300 Å (530 nm) and 5600 Å (560 nm) represent wavelengths with high extinction coefficients (ϵ) and dominant absorption (low scattering) effects. This conclusion is inescapable in light of the fact that of all the illustrated wavelengths, the one with the lowest value of ϵ (5.2) and the most illustrated non-linearity is the 5050 Å curve of Figures 2 and 6 which, however, Anderson still refers to as a coefficient which is "quite high" (page 178, line 4).

As we have noted, supra, claim 1 does not recite the degree to which scattering must be minimized. Moreover, while appellants' Figure 5 showings appear to indicate less scattering at similar 506 mm (5060 Å) and 560 mm (5600 Å)) wavelengths (in terms of more linearity than Anderson shows), the fact that the

concentration of hemoglobin and the depth of the sample also effect linearity must be kept in mind. There is no indication in appellants' Figure 5 as to the depth of the sample and the concentration of "(g/dl)" is not explained and appears different from the millimole/litre concentration used by Anderson. Accordingly, we can find no basis for the assertion of page 7 of the main brief "that there are several wavelengths with low extinction coefficients which also may minimize scattering" and the similar assertion on page 14 of the brief (note lines 8-10).

Turning back to the consideration of the teachings of Brown and Anderson taken together, we first note that teachings and not direct substitutions of structure from one reference to the other are the concern. Moreover, we note that express suggestions as to substitutions from one reference into another are not required. We, thus, find appellants' emphasis on the dissimilar structures of these references at pages 11 and 12 of the main brief and the "suggestion" arguments starting at page 15 of that brief to be without merit in light of the above noted Keller decision (which clearly indicates that the standard of obviousness does not involve only express suggestions or substituting structures from one reference into another). See also In re Nievelt, 482 F.2d 965, 179 USPQ 224 (CCPA 1973) as to combining teachings and not physical structures of the references and In re Sernaker, 702 F.2d 989, 995, 217 USPQ 1, 6 (Fed. Cir.

1983) as to acceptable express or implicit suggestions. Our concern, therefore, is not with somehow combining the specific structures shown by the references; instead, we are concerned with the concepts fairly taught and suggested thereby and whether these concepts would have suggested (expressly or by implication) the method subject matter being claimed. See, e.g., In re Bascom, 230 F.2d 612, 109 USPQ 98 (CCPA 1956); In re Shepard, 319 F.2d 194, 138 USPQ 148 (CCPA 1963) and In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979).

Turning to a consideration of such concepts, we first note appellants are correct that Brown provides no particular reasons for selecting the frequencies used for solving for the blood hemoglobin component species taught therein. However, this can only be reasonably interpreted to imply that the reasons behind the selections are conventionally known or that the selected frequencies are of no real concern in solving for the hemoglobin species. In this respect, we again note that while appellants set forth generalities in the specification as to frequency selections being related to improving measurement accuracy, etc., such subject matter has not been expressly claimed and is not before us. Moreover, the specification provides no guidance in achieving such results much less any yardsticks to judge them by, all as fully detailed above. Accordingly, we find nothing demonstrative of unobvious subject

matter in the failure of Brown to set forth reasons for selecting particular frequencies offered therein as exemplary.

Anderson's teachings clearly include the concept that frequencies of radiation for use in analyzing whole undiluted blood should be selected such that scattering is minimized and absorption is maximized. Anderson also teaches that a thin or reduced depth sample is needed to further reduce scattering and that all radiation from the sample, or at least as much as possible, should be collected for detection.

Brown's teachings, to be considered with those of Anderson, relate to the advantageous use of plural detecting frequencies and equations to enable the detection of constituent hemoglobin components under a Beer-Lambert style analysis, i.e., where absorption is dominant and scattering effects have been reduced. It is manifest that Brown uses haemolysed blood to insure sufficient absorption and reduced scattering effects for this analysis to be valid. However, this does not mean that the teachings of Anderson (as to using a greatly reduced depth of the sample and a wide range detector to collect as much radiation, even scattered radiation, as possible along with the use of radiation analyzing frequencies of minimal scattering effect (dominant absorption and high extinction coefficients) to analyze, at least in part, the constituents of nonhaemolysed blood would not have been meaningful to the artisan.

In this respect, we are of the view that the artisan must be presumed to have been of sufficient skill to have recognized the clear advantage and relative simplicity of blood handling associated with the Anderson use of undiluted blood compared to the complexities of preparation and handling associated with the diluted blood required by Brown. We are also of the view that this same artisan would not have ignored the teachings of Brown as to the clear advantageous solving for plural component constituents with plural frequencies. In this respect, it is well settled that the artisan is presumed to be able and motivated, by at least common sense, to optimize known result dependent variables, such as the selection of these plural frequencies, so that the Anderson requirement of high extinction coefficients (low scattering, high absorption) would have been met. Note, In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In view of the foregoing, we will sustain the rejection of claim 1 and claims 2 to 7 will fall therewith, as noted above.

Turning to claims 8 to 12, appellants argue that because neither applied reference specifically mentions light emitting diodes (claim 8), controlled monochromators (claim 9) or controllable diffraction gratings (claim 10) as potential radiation frequency sources, the use of these sources would not have been obvious to the artisan. We disagree.

It is manifest from appellants' terse and broad disclosure of these possible radiation sources (page 7, line 28 - page 8, line 50 of the specification) that they are all conventionally known to the artisan. Note again In re Fox, supra. Moreover, appellants' specification presents no particular criticality or problem being solved in terms of using any of these alternatively suggested conventional sources. Accordingly, we consider the use of any of these known sources under these circumstances as mere design choice, see In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975), and will sustain the rejection of claims 8 to 10.

With respect to claims 11 and 12, we find, contrary to appellants' arguments, that Brown clearly teaches that a separate frequency is required for each constituent component to be determined due to the equations to be solved (which are also appellants' equations to be solved, as noted above). We are well aware that the reply brief attempts to equate the mere recital of an equal number of frequencies and constituent components to be detected (claim 11) to something of far narrower scope. However, we find it to be a broad statement which reads on the fact that four wavelengths are used to determine, in any manner, four species as set forth on the bottom of page 5 of the reply brief.

Lastly, we note that although appellants indicated claims 3 to 5 are to stand or fall with claim 1 (as part of the

group of stand or fall claims 2 to 7), appellants also offer some arguments relative to these claims. In light of the clear statement that "[c]laims 2-7 stand or fall with claim 1" and the requirement of 37 CFR 1.192(c)(5) as to a statement to the contrary, we will not treat these arguments. See also Ex parte Ohsumi, 21 USPQ2d 1020 (BPAI 1991) and Ex parte Schier, 21 USPQ2d 1016 (BPAI 1991).

Since the examiner's rejection of claims 1 to 12 under 35 U.S.C. § 103 has been sustained, the decision of the examiner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR 1.136(a). See the final rule notice, 54 F.R. 29548 (July 13, 1989), 1105 O.G. 5 (August 1, 1989).

AFFIRMED

James D. Thomas)
Examiner-in-Chief)
)
)
)
Kenneth W. Hairston) BOARD OF PATENT
Examiner-in-Chief) APPEALS
) AND
) INTERFERENCES
)
Raymond F. Cardillo, Jr.)
Examiner-in-Chief)

Arnold, White & Durkee
P. O. Box 4433
Houston, TX 77210